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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,350	08/01/2003	Jude A. Kral	ST8724US	3716

22203 7590 12/23/2005

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EXAMINER

SHAFFNER, FRANK C

ART UNIT PAPER NUMBER

1744

DATE MAILED: 12/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/633,350

Applicant(s)

KRAL ET AL.

Examiner

Frank Shaffner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date. _____  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 4 is objected to because of the following informalities: in claim 4, "with type" should be "with the type". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is indefinite because it is unclear as to if the controller determines where a connection is to be made or if a connection is proper or improper. Also, it is unclear as to whether the controller determines a predetermined pressure or if this pressure is inputted into the controller.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Based on the examiner's best interpretation of the applicant's claims:

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5. Claims 1, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weber et al. in view of Mapson et al., and further in view of Malkin et al.

Regarding claim 1, in U.S. Patent 5,761,069, Weber et al. teach a system for monitoring fluid circulation in a reprocessor apparatus for sterilization (Abstract, column 1 lines 7-9) where there are fluid connections (column 14 lines 57-60). The monitoring system comprises a pressure sensor for sensing a pressure and generating an electrical signal indicative of a sensed pressure (column 12 lines 24-31), and a controller (column 4 lines 55-57) responsive to the electrical signal (column 12 lines 30-31). Weber et al. teach the pressure sensed is indicative of the failed circulation pump (column 12 lines 26-29), however, Weber et al. fail to teach the importance of ensuring the connections within the reprocessing system are secure.

In U.S. Patent 6,485,684, Mapson et al. teach a reprocessing system for endoscope sterilization in which the exterior surfaces of endoscopes are sprayed with sterilant and the inner lumens are pressurized with sterilant through connected tubing (Abstract). Instruments such as endoscopes have a plurality of openings, and require that sterilant is flowed through different openings at different pressures. Additionally, some lumens do not need to be sterilized and would be damaged when contacted by fluids (column 1 lines 29-40). When improper connections are made between sterilant tubes and medical instruments, assurance that the sterilant is contacting all microorganisms in the lumens is lost (column 1 lines 49-52), leaving the instrument contaminated. Mapson et al. also teach using a leak detector in the reprocessing system to determine if the lumen is holding a preselected vacuum or positive pressure (column 4 lines 24-27). This shows the importance of having a fully pressurized system to expose all

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microorganisms to sterilant and ensuring certain parts of instruments are not contacted by fluids.

A decrease in fluid pressure within the system would be evidenced by an improper connection.

In U.S. Patent Application Publication 2004/0091389 A1, Malkin et al. teach that in a flexible endoscope steam sterilization system, pressure tests can be run to determine the channels or lumens that are connected with the steam sterilant source (paragraph 48).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the pressure sensor in Weber et al.'s invention to determine if there is an improper connection between the medical instrument and the sterilant ports because an improper connection would lead to fluid pressure and sterilant losses, thereby increasing the expense to operate Weber et al.'s reprocessor apparatus. Additionally, a proper connection would have been beneficial to Weber et al.'s reprocessor because it would have further ensured that medical instrument sterilization was complete by leaving no part of the instrument contaminated as taught by Mapson et al. above, which is a concern since Malkin et al. teach the complexity of the inner parts of endoscopes (paragraph 8).

Regarding claim 5, Weber et al. teach the controller workstation comprises a keyboard (column 6 lines 26-28).

Regarding claim 6, Weber et al. additionally teach the input unit allows input of information for selecting the type of device being sterilized (column 5 line 66-column 6 line 6). Inserting a diskette and inputting information into the keyboard will allow the user to select the reprocessing unit to use based on the device being sterilized (column 7 line 62-column 8 line 31).

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6. Claims 2-4 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weber et al. in view of the combination of Mapson et al. and Malkin et al. as applied to claim 1 above, and further in view of Moser.

Regarding claim 2, Weber et al. additionally teach a display unit for indicating the status of various components of the reprocessing unit (column 8 line 64-column 9 line 1). However, Weber et al. fail to teach displaying the location in the reprocessor apparatus where an improper connection has been detected.

In U.S. Patent 5,279,799, Moser et al. teach a sterilization system for endoscopes in which endoscope ducts are checked for clogs. When a clogged duct is determined, the specific duct is indicated on a display field of the control unit (column 6 lines 15-18).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to display the location of an improper connection found in Weber et al.'s reprocessor apparatus on the screen display just as the clogged duct location was displayed in Moser's invention to notify the user of which connection is improper so the connection can be made proper, thereby increasing the response time for operators to make the reprocessor safe from spilled sterilant. This would have also aided in preventing the shutdown of all the reprocessors at once to correct the connection, since Weber et al. teach that all four reprocessors could be controlled and monitored simultaneously (column 8 lines 22-26).

Regarding claim 3, Malkin et al. further teach that the central processor responds with error messages, status notifications, and the like at the user interface display (paragraph 80). It would have been obvious to one having ordinary skill in the art at the time the invention was made to display corrective actions on the display screen of Weber et al.'s invention to aid

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hospital users who are new to using the reprocessor apparatus in correcting a connection problem, which, as Malkin et al. teaches, would contribute to faster-acting sterilization (paragraph 11).

Regarding claim 4, Weber et al. teach displaying information associated with the type of medical instruments being reprocessed (column 5 lines 7-10, column 9 line 61-column 10 line 9).

Regarding claim 7, Weber et al. in view of Malkin et al. teach the controller would determine the connection of medical instruments to sterilant sources as described above. Moser discloses that a leaking endoscope will result in a pressure drop and that an endoscope with no leaks will increase pressure (column 5 lines 34-49), making a leak intrinsic to an improper connection because the pressure sensors are connected to the line entering the endoscope (column 5 lines 18-23). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to conclude that a proper connection is obtained when the pressure increased in the medical instrument. Moser also teaches a predetermined pressure of 0.20 bar is reached and the controller makes the appropriate pressure reductions (column 5 lines 34-38).

Regarding claim 8, Moser teaches an alarm is triggered when there is a leak in the endoscope (column 5 lines 49-50). It would have been obvious to one having ordinary skill in the art at the time the invention was made to implement an audible alarm so that users that were not looking directly at the screen or working on other operations in the control room could be notified promptly, eliminating the consequence of being alerted too late and endangering personnel with leaking sterilant.

Regarding claim 9, Moser teaches that a pressure value associated with an improper connection is lower than 0.18 bar and a pressure higher than 0.18 bar is associated with a proper connection (column 5 lines 34-49).

***Conclusion***

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. In U.S. Patent 5,738,824, Pfeifer discloses a method for disinfecting surgical tools and determining the penetrability of each tool.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Shaffner whose telephone number is (571) 272-5568. The examiner can normally be reached on Monday through Friday, 7:30 AM until 4:30 PM.

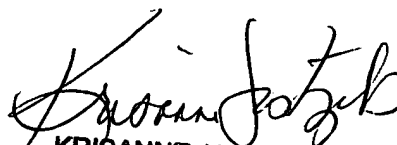
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on (571) 272-1226. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FL

FS

December 21, 2005

  
KRISANNE JASTRZAB  
PRIMARY EXAMINER